UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge Oral Argument Requested

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO PRECLUDE OPINIONS OF DEFENSE EXPERT LEE-JEN WEI, PH.D.

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Pursuant to Federal Rules of Evidence 104, 403, and 702, Defendants' Executive Committee, on behalf of all Defendants in this litigation, submit this Memorandum of Law in Opposition to Plaintiffs' Motion to Preclude Opinions of Defense Expert Lee-Jen Wei, Ph.D.[1] In support of their Opposition, Defendants state as follows.

INTRODUCTION

Plaintiffs' Motion to Preclude Opinions of Defense Expert Lee-Jen Wei, M.D. ("Motion") fails to identify any cognizable ground to exclude Dr. Wei's opinions under Rule 702. The recognized restrictions on expert testimony concern the expert's qualifications, the reliability of the expert's methodology, and the fit of the expert's opinions to the case. Plaintiffs do not attack Dr. Wei's qualifications, for good reason. Likewise, Plaintiffs do not attack the fit of Dr. Wei's opinions to the case. Instead, Plaintiffs criticize Dr. Wei's methodology based on the following arguments—none of which is sufficient to exclude his opinions under Rule 702. First, Plaintiffs assert that Dr. Wei's methodology is not generally accepted in the scientific community because his standards are too restrictive because he (1) criticizes observational studies that do not include a model fit assessment, (2) criticizes the meta-analysis of observational studies that fail to assess each study

[1] *See* Ex. A ("Wei Report" or "Wei Rep.").

used in the analysis; and (3) criticizes Dr. Madigan's use of p-values alone to reach a conclusion on the statistical significance of a study. Second, Plaintiffs claim that Dr. Wei's methodology is unreliable because he had preconceived notions about the case and worked toward achieving a desired result. Both attacks against Dr. Wei's methodology fail to satisfy Rule 702's standard for the exclusion of expert testimony.

Plaintiffs' expert statistician, David Madigan, Ph.D., attempts to use dietary and occupational studies with NDMA exposure to reach flawed conclusions regarding the risk of cancer from NDMA in valsartan. Dr. Wei reviewed the same materials Dr. Madigan reviewed and concludes that Dr. Madigan used a flawed methodology in reaching his conclusions. Contrary to Plaintiffs' contention, Dr. Wei's criticisms of Dr. Madigan's analysis of observational studies, and meta-analyses using observational studies, are rooted in statistical principles. Courts in this Circuit, and indeed across the country, have recognized the shortcomings of observational studies, specifically in the context of associating exposure to a drug or chemical to a medical condition. This problem is amplified here even more so where the observational studies are not in fact reporting on the risk of NDMA in valsartan, but are studies assessing the risk of cancer from NDMA in various foods and occupational exposures. Courts in this Circuit have emphasized the need for experts utilizing such studies to carefully examine the various factors that may impact the

study's ability to reliably indicate such an association. Dr. Wei's so-called "restrictive" standards serve this purpose and buttress the reliability of his methodology as recognized by the courts (while also highlighting the problems with the methodology of Dr. Madigan).

Dr. Wei's criticism of Dr. Madigan's use of p-values to reach conclusions as to statistical significance is also rooted in established principles of statistics, as recognized by the American Statistical Association. Plaintiffs' attempt to pit Herman Gibb, Ph.D. (Defendants' expert epidemiologist) against Dr. Wei rings hollow as both Dr. Gibb and Dr. Wei acknowledge that p-values should not be used as the sole metric for determining statistical significance. Plaintiffs' suggestion that Dr. Gibb contradicted Dr. Wei is based on a misreading of Dr. Wei's report and is simply not supported by the testimony of Dr. Wei or Dr. Gibb. Moreover, Plaintiffs' insistence that Dr. Madigan did not reach ultimate conclusions based on a study's statistical significance is false. *See* Ex. B ("Madigan Report") ¶ 35. And it also misses the point. Dr. Madigan's specific conclusions as to the statistical significance of a study's findings, which *were* based solely on the p-value, show a flaw in Dr. Madigan's methodology in reaching his ultimate conclusions. This is what Dr. Wei addresses. Dr. Wei's methodology is sound in every respect, and Plaintiffs' motion to preclude his testimony on this ground should be denied.

With respect to Plaintiffs' second broad criticism of Dr. Wei's testimony, the

Court should likewise determine that such criticisms do not warrant exclusion of Dr. Wei's opinions, namely because they are not criticisms of Dr. Wei's methodology but rather an attack on his credibility. Such attacks are reserved for cross examination. Plaintiffs' conclusion that Dr. Wei had "preconceived notions" about the case based on certain sentences of his report being the same as sentences in prior reports authored by Dr. Wei is groundless. Dr. Wei did not prejudge the case, and his methodology is scientifically sound. Finally, Plaintiffs' additional seemingly throwaway criticisms—regarding Dr. Wei's background discussion of randomized clinical trials in his report, Dr. Wei not being able to recall the abbreviation for a specific measurement during his deposition, or any specific document he was given showing the level of NDMA in valsartan containing drugs—also go to credibility, not to the reliability of Dr. Wei's methodology. Plaintiffs' criticisms offer no cognizable grounds to exclude Dr. Wei's testimony under Rule 702. Dr. Wei is qualified, his methodology is reliable, and his opinions fit the case. The Court should deny Plaintiffs' Motion in its entirety.

LEGAL STANDARD

Under Rule 702, a witness who is "qualified as an expert by knowledge, skill, experience, training, or education" may offer opinions in a case if (i) the expert's "scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"; (ii) "the testimony is based

on sufficient facts or data"; (iii) "the testimony is the product of reliable principles and methods"; and (iv) "the expert has reliably applied the principles and methods to the facts of the case." *See* Fed. R. Evid. 702. The Third Circuit has explained that Rule 702 "provides for 'a trilogy of restrictions on expert testimony: qualification, reliability, and fit.'" *R.D. v. Shohola, Inc.*, 2019 WL 6053223, at *3 (M.D. Pa. Nov. 15, 2019) (quoting *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316, 321 (3d Cir. 2003)). Under Rule 702, the trial judge acts as a "gatekeeper" to ensure that before it is presented to a jury, expert testimony is "both relevant and reliable." *Id* . (quoting *Buzzerd v. Flagship Carwash of Port St. Lucie, Inc.*, 669 F. Supp. 2d 514, 519 (M.D. Pa. 2009) (citing *Daubert*, 509 U.S. at 589)). In cases where a party objects to the admissibility to proffered expert opinion testimony, the court must examine qualifications, reliability, and fit. *Id.* (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741-47 (3d Cir. 1994) ("*Paoli II*")). In other words, a qualified expert's "testimony must [(1)] be based on sufficient facts and data; (2) must be the product of a reliable methodology; and (3) must demonstrate a relevant connection between that methodology and the facts of the case." *Id.* (quoting *Jaasma v. Shell Oil Co.*, 412 F.3d 501, 513 (3d Cir. 2005)).

In determining whether proposed testimony is sufficiently reliable, courts are to consider the following factors: (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known

or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. *Id.* (citing *In re Paoli R.R. Yard Pcb Litig.*, 35 F.3d 717, 742 n.8 (3d Cir. 1994)).

The requirements of Rule 702 must be applied with the same "'liberal thrust' of the Federal Rules of Evidence and their 'general approach of relaxing the traditional barriers to opinion testimony.'" *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593 (1993). To be admissible, "the basic minimum is that there must be some scientific validation of the theory advanced by the expert." *Id.* (citing *Daubert*, 509 U.S. at 593); *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777 (3d Cir. 1996) ("in placing restrictions on [expert's] testimony because he did not possess the exact background the court deemed appropriate, it erred").

Scientific disagreement is not sufficient grounds for the exclusion of expert witness testimony and is not for the Court to decide in its capacity as a gatekeeper under Rule 702 or *Daubert*. *See, e.g., In re Gabapentin Patent Litig.*, MDL Dkt. No. 1384, 2011 WL 12516763, at *10 (D.N.J. Apr. 8, 2011) (concluding that disagreement between experts regarding application of a methodology presents "a battle of the experts" to be resolved by the trier of fact); *U.S. v. W.R. Grace*, 455 F.

Supp. 2d 1196, 1199 (D. Mt. 2006) (Expert testimony even as to disputed evidence is admissible under Rule 702: "It appears that there is some scientific disagreement. . . It is not the Court's role to settle scientific disputes. . . . [I]t is an issue going to the weight of the evidence, and is best left to the jury"); *see also Broe v. Manns*, No. 15-985, 2016 WL 7048988, at *4 (M.D. Pa. Dec. 5, 2016) ("Any disagreement plaintiffs have with the expert can be dealt with through cross-examination, presentation of contrary evidence and proper jury instructions"); *In re Asbestos Prods. Liab. Litig*., 714 F. Supp. 2d 535, 544 (E.D. Pa. 2010); *In re Diet Drugs Prods. Liab. Litig.,* MDL No. 1203, 2000 WL 962545, at *13 (E.D. Pa. June 28, 2000) (finding that disagreement with the methods used by an expert is a question that "goes more to the weight of the evidence than to reliability for Daubert purposes").

ARGUMENT

I. DR. WEI EMPLOYED A RELIABLE METHODOLOGY IN FORMULATING HIS OPINIONS.

As noted, Plaintiffs do not criticize Dr. Wei, a Professor of Biostatistics at Harvard, on his qualifications or the fit of his opinions to the case. Instead, Plaintiffs argue that Dr. Wei's opinions should be excluded because (1) his opinions are not generally accepted in the scientific community and (2) his opinions are derived from preconceived notions. *See generally* Motion. Plaintiffs argue that Dr. Wei's opinions are not generally accepted in the scientific community because Dr. Wei, according

to Plaintiffs, inappropriately criticizes (1) observational studies that do not contain a model fit assessment, (2) meta-analyses of observational studies that fail to assess each study used in the analysis, and (3) the use of p-values alone to determine the statistical significance of a study. Dr. Wei's criticism of these studies is justified and in line with acceptable scientific methodology.

A. Dr. Wei's Criticism of Observational Studies, Meta-Analyses of Observational Studies, and the Reliance on P-Values to Assess Statistical Significance Is the Product of Sound Methodology.

Plaintiffs' criticism of Dr. Wei's standards as too restrictive and "unattainable," *see* Motion at 7, ignores the noted problems associated with observational studies in the context of pharmaceutical litigation. At the general causation stage, experts should primarily rely on epidemiological studies to test their theory that exposure to the drug or chemical at issue caused the subject condition. *See, e.g.*, *In re Avandia Mktg.*, MDL No. 1871, 2011 WL 13576, at *2 (E.D. Pa. Jan. 4, 2011); *see also Soldo v. Sandoz Pharms. Corp.,* 244 F. Supp. 2d 434, 533 (W.D. Pa. 2003) (noting "[t]he need for statistically significant epidemiology is particularly acute" in a case where the disease occurs in the general population in order "to determine whether any given case of [the disease] could possibly be attributable to a particular drug"); *see also In re Roundup Prod. Liab. Litig.,* 390 F.Supp.3d 1102, 1116 (N.D. Cal. 2018) ("Epidemiology is . . . central to the general causation inquiry"); *Burleson v. Tex. Dep't Criminal Justice,* 393 F.3d 577, 585-86 (5th Cir.

2004) (upholding exclusion of expert causation testimony where expert relied solely on studies showing certain cancers were "associated with" exposure to substance at issue but lacked epidemiological studies establishing causation). Double-blind randomized control trials, and particularly monotherapy trials, are the "gold standard" of epidemiology. *See In re Avandia Mktg.*, 2011 WL 13576, at *2. Sometimes, however, such studies may not ethically be conducted, and research may have to rely upon "less rigorous observational studies." *See In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, MDL No. 23422015 WL 7776911, at *2 (E.D. Pa. Dec. 2, 2015), *aff'd sub nom. In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017).

The best observational studies are designed and powered to test the outcome of interest. But where individual studies are underpowered, studies can sometimes be combined using a meta-analysis to increase the power. *See id; see also In re Avandia Mktg.*, 2011 WL 13576, at *3 ("To overcome the problem of underpowered studies, researchers may combine data from several studies into a meta-analysis."). "In some cases the science must proceed based upon less rigorous methods." *In re Avandia Mktg.*, 2011 WL 13576, at *3. "This does not mean that inferences about causation cannot be made; it simply means that *the expert must more carefully examine possible sources of bias or confounding and other factors which may make the study a weak indicator of causation*." *Id.* (emphasis added). This is exactly what

Dr. Wei's methodology does.

1. Model Fit Assessment of Observational Studies

Dr. Wei fully explained the reasons why he considered but ultimately gave less weight to the observational studies on which Plaintiffs' experts rely. *See* Wei Report ¶ 15. As a threshold matter, the inquiry at this stage is whether the NDMA level to which valsartan patients could reasonably have been exposed increases the risk of cancer. With this framework, it is clear why sound methodology would include verifying a model fit assessment. The dietary and occupational studies used by Plaintiffs' expert are not designed to test the "outcome of interest." *In re Zoloft*, 2015 WL 7776911, at *2. **That is, those studies do not evaluate nitrosamines in valsartan containing drugs (VCDs).** Plaintiffs' expert Dr. Madigan attempts to use an unreliable methodology in using dietary and occupational exposure studies evaluating NDMA to reach conclusions about NDMA containing valsartan. It is Dr. Madigan's methodology that is unreliable, and Dr. Wei is criticizing it. As such, as Dr. Wei notes, it is necessary to verify that there was an assessment of how the results of any such study relate to the question at issue in this case, i.e., whether the NDMA in any VCDs increases the risk of cancer.

> I think we have to be very careful to actually figure out how we can use one type of study, and we can extrapolate the result to another compound. [The dietary studies are] not relative to valsartan, right. And you cannot just directly say, well, we see from association from [a] dietary [study]. It is not automatically claiming we have [an] issue with valsartan.

See Ex. C. ("Wei Dep.") at 363:10-19.

> You cannot use only one single independent data. . . . [Y]ou have to use another independent observational study to validate the model before clear or not. That is a well known fact now, right. The training, the validation set independent of datasets.

Wei Dep. 348:5-13.

Plaintiffs' claim that Dr. Wei "ignored [epidemiological studies that demonstrate a link between NDMA exposure and an increased risk of cancer] without providing a scientifically satisfactory explanation to justify his exclusion of these studies" (*see* Motion at 6) is simply inaccurate. Dr. Wei evaluated each of the observational studies to determine if a model fit assessment was conducted. He applied this standard consistently across the board, and he explained his reasoning for doing so during his deposition, as noted above, and also in his report. *See* Wei Report ¶ 20. Moreover, Dr. Wei further identified the circumstances under which he would give more weight to such observational studies in the absence of a model fit assessment.

> Q: I believe it's your testimony that even if the vast majority of observational studies do not provide a comprehensive description of model fitness assessment, you would not give reliability to those observational studies, correct?
>
> A: I would put very little weight on their findings. I don't really trust the result with just [a] single study. **I [would] probably need a validation study**.

Wei Dep. 357:19-358:6. (Emphasis added). Dr. Wei did not ignore evidence, as

Plaintiffs suggest, or cherry-pick. He "carefully examine[d] possible sources of bias or confounding and other factors which may make the study a weak indicator of causation" as courts in this Circuit acknowledge is proper for an expert to do when evaluating observational studies. *In re Avandia Mktg.*, 2011 WL 13576, at *3. He reviewed all the same studies Dr. Madigan evaluated. All of the studies were on Dr. Wei's reliance list, and he discussed those studies in his report. *See* Wei Report, Exhibit B. The fact that Dr. Wei's methodology leads to a conclusion unfavorable to Plaintiffs' case does not warrant exclusion. "The fact that Plaintiffs' experts and defendants' experts reach different conclusions does not factor into the Court's assessment of the reliability of their methods. The experts must use good grounds to reach their conclusions, but not necessarily the best grounds or unflawed methods." *Id.* at *3.

2. Dr. Madigan's Failure to Check the Models Utilized in Meta-Analysis

In addition to explaining why he gave little weight to observational studies without a model fit assessment, Dr. Wei also explained why it is necessary to check the adequacy of the models used in the observational studies in the meta-analysis. Again, when researchers rely on less rigorous observational studies, they must "*more carefully* examine possible sources of bias or confounding and other factors which may make the study a weak indicator of causation" to draw inferences of causation. *In re Avandia Mktg.*, MDL No. 1871, 2011 WL 13576, at *3 (E.D. Pa. Jan. 4, 2011)

(emphasis added). As Dr. Wei noted in his deposition, there would be no need to check the adequacy of the models of a meta-analysis of clinical trial results, which are the gold standard. "Most meta-analysis I [deal] with [use] clinical trial results . . . . So, in that case you don't have to make adjustment, because basically they are balanced, right, between the two groups comparatively. So, usually we don't worry about this so-called model checking, because there is no model" Wei Dep. 376:2-10. The same is not the case for observational studies. "It is known that such observational studies have inherent issues in the valid assessment of the exposure since we cannot guarantee the comparability between two groups at the subjects' baseline factors." Wei Report ¶ 20. "It is not clear one can ensure that those groups are only different with respect [to] the exposure levels, but not for other factors. *Id.*

Plaintiffs assert that Dr. Wei "acknowledged that [an analysis of the models utilized in a meta-analysis] was rarely applied to any meta-analysis of observational studies" (*see* Motion at 8) and that this renders his opinion excludable as not generally accepted. But a less-commonly employed methodology does not render the methodology not generally accepted. This is particularly true here given the noted problems of observational studies, which are well known in the scientific community and long recognized by the courts. The fact that Dr. Wei applied a more rigorous standard when evaluating these studies, and meta-analyses using observational studies, does not undercut the reliability of his methodology, and it

does not render it not generally accepted.

3. Use of P-Value as Sole Criterion to Determine Statistical Significance

Plaintiffs also assert that Dr. Wei's criticism of Dr. Madigan's reliance on p-values to determine the statistical significance of study is not based on reliable principles and methods. As support for this point, Plaintiffs point to deposition testimony of Defendants' expert epidemiologist, Herman Gibb, Ph.D., and argue that Dr. Gibb contradicts Dr. Wei with respect to the unreliability of p-values. *See* Motion at 10-11. The testimony highlighted by Plaintiffs, however, simply does not show a contradiction. Dr. Gibb testified that p-values are "*probably not the only thing you want to look at*, but it . . . is certainly what is commonly used in epidemiologic studies and it will continue to be used." *See* Ex. D ("Gibb Dep.") at 61:2-5. (Emphasis added). Dr. Wei's complete opinion regarding p-values—not just the portion Plaintiffs' cite from the Executive Summary of his Report—makes it clear that the criticism is of Dr. Madigan *solely* basing his conclusions on whether the p-value was less than .05 or not. *See* Wei Report ¶ 29. Dr. Wei further expounded on this in his deposition:

> The American Statistical Association, if you read it very carefully, they are just telling us, don't use a single metric, which is P [-value] less than 05, to make a black and white claim for statistical significance.
>
> We should utilize other judgment, for example, from clinical input . . . and from subject matter people.

. . .

> So, basically, [Dr. Madigan] agrees with ASA statement, saying we should not use P less than .05 or 95 percent confidence interval, excluding null value or not, to make a decision. And broader, we should look at the entire totality of evidence to make a decision. So that's the point.

Wei Dep. 309:23-310:23. Dr. Gibb's testimony is consistent with Dr. Madigan's testimony on this point. It is inaccurate and misleading to claim that the two experts are at odds.

Moreover, Plaintiffs miss the point of Dr. Wei's criticism of Dr. Madigan's reliance on p-values. First, Dr. Madigan *did* reach ultimate conclusions based on a study's statistical significance. *See, e.g.*, Madigan Report ¶ 35. But this is a separate issue from whether Dr. Madigan's specific determination as to the statistical significance of a study's findings were based solely on the p-value, which they were. A review of Dr. Madigan's report makes this clear. *See* Madigan Report at p. 7, Table 1. In short, Plaintiffs issues with Dr. Wei's criticisms of observational studies and Dr. Madigan's use of p-values does not warrant the exclusion of Dr. Wei's opinions. His methodology is sound.

B. Dr. Wei's Opinions Are Not Based on Preconceived Notions.

Plaintiffs' final criticism of Dr. Wei's opinions is that Dr. Wei's opinions are derived from preconceived notions and are therefore unreliable. *See* Motion at 11. Specifically, Plaintiffs claim that Dr. Wei copied sections of his report from previous

reports; includes a discussion in his report of clinical studies, which Plaintiffs surprisingly argue is not relevant; was not able to recall the abbreviation for specific measurements during his deposition; and did not recall during his deposition certain documents specifying the levels of NDMA in valsartan containing drugs. Although Plaintiffs assert these arguments as going to the reliability of Dr. Wei's opinions, each actually goes to credibility and as such is an insufficient ground to exclude Dr. Wei's testimony.

1. Copy and Pasted Sections of Report

Plaintiffs' first issue is with "copy-and-pasted" sections of Dr. Wei's report. *See* Motion at 11. Plaintiffs exaggerate this alleged problem. "The extensive duplicative language between Dr. Wei's Valsartan report and reports from previous litigations are discussed for fifty-six pages throughout the first day of the deposition." *See* Motion at 13. It is worth pointing out that Dr. Wei's opinions in his report only span twenty-four (24) pages. Importantly, the fact that sections of Dr. Wei's report may be pasted from his prior work on other cases does not mean that his opinions should be excluded as unreliable. An expert is not required to reinvent the wheel every time he writes a report, particularly if certain aspects of the analysis are the same. *See, e.g.*, *Salinero v. Johnson & Johnson*, 2019 WL 7753453, at *5 (S.D. Fla. Sept. 5, 2019) (denying motion to exclude expert whose report in transvaginal mesh case was largely copy-pasted in abdominally implanted mesh case

as opinions would be the same regardless of implantation method, opinions were not unreliable, and defendants had ability to cross-examine expert). The same reasoning applies here. Dr. Wei's methodology is reliable, and Plaintiffs have the ability to cross-examine him about any alleged copy and pasting from his previous work product. Moreover, the portions of Dr. Wei's report that are copied and pasted relate to general background statistical principles that remain unchanged from his prior reports, not his conclusions about valsartan. Plaintiffs' experts do the same. This is not a reason to exclude Dr. Wei's testimony.

2. Background Information on Clinical Trials

Plaintiffs also half-heartedly criticize Dr. Wei for including background information on clinical studies in his report. *See* Motion at 14. Plaintiffs assert, without justification, that Dr. Wei included the discussion on clinical trials in his report because they were used in prior litigations in which Dr. Wei served as an expert. *Id.* Dr. Wei's decision to include relevant background information on the hierarchy of epidemiologic studies in his report—of which clinical trials are the gold standard—clearly lays the foundation for why he employs heightened standards in assessing the observational studies at issue. *See* Wei Report at 9-10. More importantly, this too is the subject of cross-examination, not a basis for exclusion.

3. Toxicology Measurements and Amount of NDMA in VCDs

Similarly, Plaintiffs' argument that Dr. Wei's failure to remember during his

deposition what certain abbreviations stood for or the amount of NDMA in VCDs does not create a ground on which to exclude his testimony. Again, this is a matter for cross-examination. "The credibility of experts is for the jury to determine. [Courts] should not generally consider an expert's credibility as a witness when assessing the reliability of his methods." *In re Mushroom Direct Purchaser Antitrust Litig.*, 2015 WL 5775600, at *8 (E.D. Pa. Aug. 5, 2015) (citing *Elcock v. Kmart Corp.*, 233 F.3d 734, 751 (3d Cir. 2000); *In re Processed Egg Prods. Antitrust Litig.*, 81 F. Supp. 3d 412, 417-18 (E.D. Pa. 2015) (following *Elcock* and declining to consider an expert's credibility at *Daubert* stage). Moreover, the fact that Dr. Wei stated that he had not calculated lifetime cumulative exposures before does not warrant exclusion of his opinions. As Dr. Wei noted, the lifetime cumulative exposure calculation is not a novel concept. *See* Wei Dep 19-23 ("[It is] not a statistical novelty because statistical [argument] is very straightforward. That's what I'm concern[ed] about his statistical argument and the claim.").

II. DR. WEI IS WELL QUALIFIED TO OFFER HIS OPINIONS.

Although Plaintiffs subtly suggest that Dr. Wei is unqualified based on the above-noted oversights, they do not argue against his qualifications. This is because Dr. Wei is without question well qualified to offer the opinions that he offers. Dr. Wei has a Ph.D. in Statistics from the University of Wisconsin. *See* Wei Report, Ex. A. He has been a professor of biostatistics at Harvard University since 1991 and a

professor of biostatistical science and computational biology at Dana Farber Cancer Institute since 1997. *Id.* He has served as an associate editor of the Journal of the American Statistical Association (Theory and Methods Section) since 2005 and has published over 230 research articles in peer-reviewed journals. *Id.* He has extensive experience designing, monitoring, and analyzing clinical studies, including studies for pharmaceuticals. *Id.* at 4. And he is responsible for developing novel statistical methods for designing, monitoring, and analyzing clinical studies, survival analyses, and meta-analyses. *Id.* He also received the Wilks Medal in 2009 from the American Statistical Association for outstanding contributions to clinical trial methodological research. *Id.* at 5. Based on his extensive experience and leadership in the field, Dr. Wei is certainly well qualified to offer the opinions he offers in this case.

CONCLUSION

Based on the above-cited authority, Defendants respectfully request that the Court deny Plaintiffs' Motion. There is no question that Dr. Wei is qualified to offer his opinions in this case. Indeed, Plaintiffs have not argued against Dr. Wei's qualifications. Likewise, there is no question that Dr. Wei's opinions will be helpful for the jury. And as shown, Dr. Wei's opinions are methodologically sound. Plaintiffs' criticisms of Dr. Wei's methodology are the result of a mischaracterization of the general causation inquiry as well as a mischaracterization of Dr. Wei's opinions and testimony. Plaintiffs have failed to point to any valid

ground to exclude Dr. Wei's opinions, and their Motion should accordingly be denied.

Dated: December 1, 2021

Respectfully Submitted by the Defense Executive Committee on behalf of all Defendants,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on December 1, 2021, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

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